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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/629,296	07/28/2003	Yasunori Kawate	11333/25	6488

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Brinks Hofer Gilson & Lione
NBC Tower
Suite 3600
P.O. Box 10395
Chicago, IL 60610

EXAMINER	
GABEL, GAILENE	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/629,296	KAWATE, YASUNORI	
	Examiner	Art Unit	
	GAILENE R. GABEL	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 January 2008 and 09 October 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *33-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *33-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Art Unit: 1641

DETAILED ACTION

Election/Restrictions

1. Applicant's election of claims 36-41, without traverse, filed on January 22, 2008, is acknowledged and has been entered. Upon further consideration, however, claims 33-36 have been rejoined for prosecution on the merits. Accordingly, claims 33-41 are pending and are under examination.

Withdrawn Rejections

2. The rejections of claims 1, 4-12, 14, and 18-25 are now moot in light of Applicant's cancellation of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

In the specification at page 2, lines 4-6, the analysis apparatus includes an automated hematology analyzer such as the Sysmex XE-2100 supplied by Sysmex Corporation. Other parameters measured by the analyzing portion of this hematology analyzer include mean corpuscular volume (MCV) which is a mean value of erythrocyte sizes in the blood sample, and hematocrit which is a measure of packed red cells occupying the blood sample (page 3, lines 4-13). The light source is a laser beam source such as a semiconductor laser beam source (page 13, lines 2-3 and page 25, lines 3-4). The light detector includes photomultiplier tubes and photo diodes (page 13, lines 4-11 and page 25, lines 7-16). The analyzing portion is a computer which includes a hard disk, CPU, ROM, RAM and the like (page 3, lines 14-16). At page 30, line 14 to page 31, line 1 of the specification, Applicant specifically provides that the entire operation from the setting of the whole blood (in the sample preparing portion) to analysis (in the analyzing portion) of the apparatus are performed according to standard measurement method with an automated hematology analyzer XE-2100 which is supplied by Sysmex Corporation.

3. Claims 33-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Oku et al. (US Patent 6,106,778) in view of Rodriguez et al. (US Patent 6,228,652). 1, 4-12, 14, and 18-25

Oku et al. disclose a compact combination blood cell count and immunoassay analyzer wherein the sample preparing portion is configured for preparation of split blood specimens, one for immunoassay section and the other for blood cell measuring section (see Abstract). The results of immunoassay, i.e. C-reactive protein (CRP), are corrected using a hematocrit value obtained by measurement of the number of blood cells (see column 1, line 62 to column 2, line 3 and 29-36; and column 7, lines 12-25). The analyzer in the immunoassay section comprises a light source (light irradiating section), a light detector (light detection section) for detecting optical information from the immunoassay, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured optical

information from the binding information between anti-CRP antibody immobilized into carrier particles (latex immunoreagent) that binds CRP protein present in the sample. The analyzer in the blood cell count section is configured to count and differentiate between leucocytes (WBC), erythrocytes (RBC), and platelets, and also to measure mean corpuscular volume (MCV) and hematocrit (Hct) using a first detector that measures electric resistance. The analyzer in the blood cell count section also comprises a light source and a second detector for detecting light irradiation section from the hemoglobin in the sample, and an analyzing portion (microcomputer with processor) for performing arithmetic computation from the measured electrical resistance measurements and optical information (see column 4, lines 18-37 and column 5, lines 6-11).

Oku et al. differ from the instant invention in failing to teach an analyzing portion for differentiating blood cells and the fluorescent carrier particles based on fluorescent intensity measurements by the first detector, counting the blood cells, and then detecting agglutination degree of the fluorescent carrier particles based on detected scattered light intensities by the second detector.

Rodriguez et al. disclose an analyzer which comprises a sample preparing portion for subjecting samples to reagent, a light source for irradiating the assay sample, light detectors: a first detector for detecting radiation scattered from irradiated blood cells and a second detector for detecting and measuring fluorescence intensities from fluorescence-labeled cell surface antigens in different subsets of cells. The analyzer further includes analyzing portions (1) for counting and differentiating between blood cell types and also (2) for determining concentration of different fluorescent-labeled cell surface antigens (assay substances) (see column 4, line 28 to column 5, line 18 and column 5, lines 34-47). The sample preparing portion is configured to subject a first and a second aliquot of samples (or a plurality of such aliquots) to different reagents. Rodriguez et al. teach subjecting each individual aliquot to different reagents such as fluorescent dyes and fluorescent-labeled monoclonal antibodies specific for the analyte (cell surface

antigens: CD4 and CD8) to be assayed or specific for blood cell surface markers in order to stain different blood cells (see column 7, line 59 to column 8, line 20 and column 11, line 46 to column 12, line 2). The light source may be any one of continuous wave laser, argon-ion laser, and diode-pumped solid state laser (see column 9, lines 26-34, column 10, lines 44-56, and column 13, lines 43-53). The different light detectors are photodetectors that correspond to different fluorescence spectra by different dyes and fluorochromes (see column 8, lines 21-65 and column 10, line 57 to column 11, line 28). The analyzing portion counts and differentiates between erythrocytes (red cells), leucocytes (fluorescent labeled subsets of white cells), and platelets (see column 5, lines 18-28 and column 7, line 58 to column 8, line 20). The analyzing portion provides a measure of hematocrit value based on size information of blood cells (MCV and RBC). According to Rodriguez et al., the analyzing portion corrects immunoassay results, such as for hemoglobin, based on blood cell counting values (MCH and RBC) (see column 8, lines 49-60 and column 14, lines 5-40). Optical information that is measured includes scattered light and fluorescence intensity from the analyte.

One of ordinary skill in the art at the time of the instant invention would have been motivated to incorporate the light detector and analyzing portion as taught by Rodriguez, into the combined blood cell count and immunoassay analyzer as taught by Oku because Oku specifically provided advantage in being able to measure blood cell differentiation and target analyte concentration in a simultaneous manner in a whole blood sample such as in emergency diagnostic medicine, whereas Rodriguez specifically taught that using an analyzer having a single light detector and analyzing portion that can measure light scatter and fluorescence from particle combinations in a sample, would also allow for simultaneous detection and analysis of light scatter and fluorescence measurements from blood cells and target analytes bound to carrier particles present in the whole blood sample.

Response to Arguments

5. Applicant's arguments with respect to the combination of Oku et al. with Rodriguez et al. have been considered but are not persuasive.

Contrary to Applicant's contention, the combination of Oku with Rodriguez appear to still render obvious the new claimed invention. See substantial discussion of the references supra.

6. No claims are allowed.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to GAILENE R. GABEL whose telephone number is (571)272-0820. The examiner can normally be reached on Monday, Tuesday, and Thursday, 8:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/GAILENE R. GABEL/
Primary Examiner, Art Unit 1641

April 14, 2008